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Delaware announces agreement with pharmaceutical firms concerning delayed disclosure of negative drug study results

Wilmington, DE – Today, the Delaware Attorney General's office announced a settlement with Merck & Co. Inc, Shering-Plough Corporation, and joint venture company MSP Singapore Company, LLC that resolves a multi-state investigation into the companies' lengthy delay releasing negative results from a clinical trial involving the cholesterol lowering drug Vytorin®. As a result of the investigation, the companies will make specific changes to their business practices and pay $5.4 million to the 36 states who participated in the investigation. Delaware's Consumer Protection Fund will receive $100,000.

"It is unacceptable for pharmaceutical companies to delay the release of study results that may influence consumers' purchasing decisions," stated Timothy Mullaney, Director of the Attorney General's Fraud and Consumer Protection Division. "As a result of this investigation, consumers will benefit from more timely and accurate information about medications available to them and be able to make better informed choices."

In the clinical trial, Vytorin, a combination of the drug Zetia® and simvastatin, was no more effective reducing formation of plaque in carotid arteries than the cheap, generically available cholesterol lowering drug simvastatin. Although the clinical trial ended in May 2006, a partial reporting of negative results did not occur until January 2008, and complete results were not published until the following April. Prior to the release of study results, Vytorin had been heavily promoted in direct-to-consumer advertisements.

Today's settlement applies the same injunctive relief to Zetia and Vytorin that was applied to Merck's 2008 Consent Judgment with the states regarding Vioxx. Zetia and Vytorin had been carved out from the Vioxx settlement because they are promoted by Merck as a joint venture with Shering-Plough. Among the injunctive relief that now applies to Vytorin and Zetia are requirements to:

- Obtain pre-approval from the Food and Drug Administration (FDA) for all direct-to-consumer television advertisements;
- Comply with FDA suggestions to modify drug advertising;
- Register clinical trials and post their results;
- Prohibit ghost writing of articles;
- Reduce conflicts of interest for Data Safety Monitoring Boards that ensure the safety of participants in clinical trials; and,
- Comply with detailed rules prohibiting the deceptive use of clinical trials.

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